

## **PMP Safflower Confinement at SemBioSys**

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Genetically engineered crop plants designed to produce pharmaceuticals and industrial proteins are quickly becoming the focus of a great deal of interest from industry and government. The technology is helping address the increasing manufacturing demand for certain biologics and industrials as well as enabling the production of others through the use of unique plant systems. The development of these crops from project initiation to commercial level production is a constant challenge. Companies must maneuver through an obstacle course of technical hurdles, weave through minefields of FTO and navigate unforgiving economical waters. In addition to these operations, the PMP industry has been placed under a very stringent level of scrutiny by government regulatory agencies since these plants are believed to present greater potential for environmental and/or human health risks. The production of PMP crops comes with great responsibility so that all regulations are followed and these risks are mitigated.

SemBioSys Genetics Inc. is a Calgary, Canada-based company that produces pharmaceutical and industrial proteins in the oilseeds of transgenic safflower plants. Much of the success of PMP production in safflower at SemBioSys is dependent on a comprehensive set of confinement measures, procedures and policies that track all material in a cradle to grave fashion. Every step of the process has been examined and is supported by the CACCP (Containment Analysis and Critical Control Points) program developed at the Biotech Industry Organization (BIO). This process as it pertains to the transgenic safflower production system at SemBioSys will be the focus of this presentation.